IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

PHHC, LLC, D/B/A PERSONAL HOME HEALTH CARE 26691 Richmond Rd. Bedford Heights, Ohio 44146 *Plaintiff*, v. ALEX M. AZAR, II, SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES 200 Independence Ave., SW Washington, D.C. 20201 and SEEMA VERMA, ADMINISTRATOR FOR THE CENTERS FOR MEDICARE AND MEDICAID SERVICES 7500 Security Blvd. Baltimore, MD 21244 and PALMETTO GBA, LLC c/o CT Corporation System 4400 Easton Commons Way Suite 125 Columbus, Ohio 43219 *Defendants*.	)	CASE NO. JUDGE **VERIFIED COMPLAINT** **INCLUDING TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION RELIEF**

Now comes Plaintiff, PHHC, LLC d/b/a Personal Home Health Care ("PHHC" or "Plaintiff"), by and through the undersigned counsel, and hereby files this Complaint against Alex M. Azar, II, Secretary of the United States Department of Health and Human Services, in his official capacity, and Seema Verma, Administrator for the Centers for Medicare and

Medicaid Services, in her official capacity, and Palmetto GBA, LLC (collectively the "Defendants") for relief in the form of Temporary Restraining Order, Preliminary Injunction, and Permanent Injunction. In support of this Verified Complaint, Plaintiff states and verifies as follows:

PARTIES

1. Plaintiff is a Medicare-certified home health agency that provides skilled nursing care, home health services, and other medical services to approximately 170 patients in their homes in Northeast Ohio, and has its principal place of business located at 6133 Rockside Road, Suite 101, Independence, OH 44131. Plaintiff provides unique in-home healthcare services to patients recovering from surgeries or illnesses, or for those unable to leave home to receive necessary medical care.

2. Defendant Alex M. Azar, II is the Secretary of the Department of Health and Human Services, the federal agency responsible with overseeing the operation of the Medicare program. Secretary Azar is sued in his official capacity.

3. Defendant Seema Verma is the Administrator for the Center of Medicare and Medicaid Services, and she is sued in her official capacity.

4. Defendant Palmetto GBA, LLC is South Carolina limited liability company, registered to do business in the State of Ohio, operating as a Medicare Part A carrier through a contract awarded by the United States Department of Health and Human Services and the Centers for Medicare and Medicaid Services ("CMS"). Palmetto processes all Medicare Part A claims relating to home health & hospice services within jurisdiction JM, which includes all Medicare Part A providers and suppliers submitting home health & hospice claims within the State of Ohio, such as Plaintiff.

JURISDICTION AND VENUE

5. This action arises under the Social Security Act, 42 U.S.C. § 301 et seq., including the Medicare Act, 42 U.S.C. § 1395 et seq. as well as the Fifth and Fourteenth Amendments to the United States Constitution.

6. This Court has jurisdiction over this case, because it is based on 28 U.S.C. §1331, 28 U.S.C. §1367, 42 U.S.C. §1395ddd(f)(2)(A) and 42 C.F.R. Part 405, Subpart I, which outlines the administrative appeals process for Medicare Part B claims. Jurisdiction is also proper in this case under 28 U.S.C. §1332, as all the parties are citizens of different states, and the amount in controversy is over Seventy-Five Thousand Dollars ($75,000.00).

7. This Court also has jurisdiction pursuant to the collateral-claim exception, as established in *Mathews v. Eldridge*, 424 U.S. 319, 326-32 (1976). As established in *Eldridge*, the Supreme Court held that jurisdiction may lie over claims (a) that are "entirely collateral" to a substantive agency decision and (b) for which "full relief cannot be obtained at a post deprivation hearing." *Id.* at 330-32.

8. The collateral-claim exception also applies to this matter as Plaintiff's claims seek relief that would be unavailable through the administrative process, as explained herein. *Eldridge*, 424 U.S. at 330-32.

9. Plaintiff's claims are collateral to Plaintiff's substantive claims in the billing dispute and appeal. Plaintiff does not request this Court resolve the merits of the underlying billing, coding, and extrapolation dispute. Rather, Plaintiff simply requests the Court preclude Defendants from engaging in recoupment based on the preliminary and disputed determinations of its own contractors until after Plaintiff has been afforded the opportunity of due process and to obtain a hearing and ruling from an impartial and unbiased Administrative Law Judge ("ALJ").

10. Plaintiff is currently challenging the billing dispute at issue through the applicable administrative process; however, the ALJs do not have the authority to issue an injunction to stay recoupment by HHS or CMS, nor do they have the authority to issue an order maintaining the status quo with regard to recoupment until a final decision has been issued by an ALJ. Accordingly, Plaintiff lacks an adequate administrative remedy at law through which it can obtain the relief it seeks in this matter, the deferment of recoupment until after Plaintiff has had the opportunity to appear before a fair, unbiased, and impartial ALJ.

11. In addition, there is no formal administrative mechanism to request deferral of recoupment before HHS or CMS, and the only other alternative, a repayment schedule, is not available to Plaintiff as a result of the continued monetary impact such large payments would have on Plaintiff, effectively having the same effect as recoupment. There is no provision in the U.S. Code or Code of Federal Regulations that provides an Administrative Law Judge ("ALJ") with jurisdiction over a Medicare Part A carrier such as Palmetto, with respect to the improper recoupment process that is occurring in this case.

12. In addition, the repayment schedule will have the same effect of causing Plaintiff's business closure and/or bankruptcy.

13. Due to the amounts that Defendants seek to recoup and the lengthy delay before a hearing can be held before an impartial ALJ, at least three (3) to five (5) years in the future, Plaintiff is facing the practical equivalent of a total denial of administrative or judicial review because the pre-hearing recoupment would certainly put Plaintiff out of business long before any ALJ hearing takes place.

14. If this Court does not issue injunctive relief, Plaintiff and its patients will have no remedy or review prior to further irreparable harm occurring.

15. This Court also has jurisdiction over this action pursuant to 28 U.S.C. § 405 under the "waiver" exception to the usual requirement of exhaustion of administrative remedies. Plaintiff has appealed and requested a hearing before an ALJ to demonstrate that the applicable home health criteria have been met, including obtaining physician certifications, face-to-face evaluations, and plans of care.

16. Exhaustion of administrative remedies under the Medicare Act is not required when a plaintiff's interest in having a particular issue resolved promptly is so great that the requirement is considered waived.

17. Venue is proper in this District under 28 U.S.C. § 1391(b), because this is the judicial district in which a substantial part of the events or omissions giving rise to the claims occurred, and this is the judicial district where a substantial part of property that is the subject of the action is situated.

INTRODUCTION

18. This is a civil action, which includes a Temporary Restraining Order and a Preliminary Injunctive relief, to order Defendants from recouping over $10,803,762.36 in alleged overpayments, plus interest, from Plaintiff, which, if permitted to occur, would bankrupt Plaintiff and cause it to go out of business well before Plaintiff has the opportunity to be heard by the Administrative Law Judge ("ALJ").

19. Defendants' recoupment of the extraordinary amounts at issue, without providing Plaintiff the opportunity to be heard timely by an ALJ, as required by applicable statute, violates Plaintiff's due process rights. Recoupment of over $10.8 million from Plaintiff, while a genuine billing dispute remains in the growing backlog of hundreds of thousands of cases pending before

the HHS Office of Medicare Hearings and Appeals ("OMHA"), will irreparably harm Plaintiff through the destruction of its business and the ensuing certain closure of its operations.

20. Health care providers, such as Plaintiff and other home health agencies, furnish services to Medicare beneficiaries and subsequently submit claims for payment to HHS, which processes the claims for payment through CMS and its contractors. The Medicare Modernization Act of 2003 ("MMA") authorizes CMS to conduct post-payment reviews of these claims through the use of its contractors to verify eligibility of the payment.

21. In a growing number of these post-payment reviews, original payment determinations are being overturned based on reviews' findings ("Redeterminations"), often based on disputed and subjective reviews, that certain services failed to meet criteria and the providers, such as Plaintiff, are informed they must refund the funds previously reimbursed ("Overpayments"), even if the review findings are ultimately found to be incorrect during the appeal process.

22. Under the MMA, providers have the statutory right to contest the post-payment denials through five-levels of appeal, with the first four levels of appeal housed within HHS, and the fifth level consisting of judicial review in a U.S. District Court.

23. The statute prescribes specific timeframes for the provider to file its appeal at each level, as well as specific timeframes in which a decision must be decided following receipt of the provider's appeal. Section 935 of the MMA also prevents recoupment of the alleged overpayment until providers have completed the second level of review ("Limitation on Recoupment"). Once this second level of review is completed, CMS may begin to recoup the alleged overpayment, despite the fact that the provider has not completed the entire five-level appeal process, including a hearing in front of an ALJ.

24. The data maintained by OMHA demonstrates that Redetermination decisions are frequently reversed, but often not until they reach the third level of the appeals process where the provider is entitled to have its claim heard by the assigned ALJ within the OMHA. This third level of appeal is the first opportunity in the appeals process for a provider's claims to be heard and reviewed by an adjudicator who is completely independent from CMS.

25. As a result of increasing audit activity, providers have experienced extraordinary delays in the appeals process, particularly at the ALJ level, which has effectively stopped and prevented providers from challenging payment denials in a timely manner.

26. Not only has this extraordinary delay affected timely submitted appeals, but it also violates the statute, which requires the ALJ to hold a hearing and issue a decision within ninety (90) days of an appeal being filed with OMHA.

27. In practice, rather than participating in a process that should take no more than one (1) year, providers are waiting between three (3) to five (5) years to have their claims heard by an ALJ. In 2014, OMHA reported an average twenty-eight (28) week delay in having claims docketed, much less holding a hearing or rendering a decision. These administrative delays violated the clear statutory mandates for the required hearing and are outside OMHA's statutory authority. As the backlog continues to grow exponentially, in the beginning of 2014, OMHA suspended the assignment of appeals to ALJs for a period of 28 months.

28. When the excessive delays and suspension of ALJ assignments are considered in conjunction with existing delays in other steps of the appeals process, the consequences are startling: providers may wait five years, or even longer, to have their claims proceed through an administrative appeals process that, by statute, should be completed by no later than one calendar year.

29. It is inconceivable, and a clear denial of Plaintiff's right to due process, that CMS may recoup over $10.8 million from Plaintiff and bankrupt its business *years* before Plaintiff has its first real and unbiased opportunity to be heard by an independent adjudicator.

30. The extraordinary amount that CMS is trying to recoup, based on a purported statistical methodology that is inherently flawed, in part, as it is based on its use of claims outside of the applicable, statutory limitation window, combined with the excessive backlog of claims before the ALJs, effectively strips Plaintiff of the administrative appeal due process to which it is entitled by statute. Without intervention by this Court, this statutorily mandated appeals process is entirely moot.

31. Importantly, Plaintiff does not ask this Court to usurp the power of the ALJ to decide any issue with respect to the underlying billing, coding, or extrapolation dispute, nor of CMS's ability to review the ALJ's decision in the fourth level of appeal. Plaintiff simply requests that this Court maintain the status quo until the completion of the administrative appeals process. Without injunctive relief, Plaintiff will be irreparably harmed before any meaningful opportunity for the administrative and judicial review to which it is entitled.

32. Plaintiff, therefore, seeks a Temporary Restraining Order and Preliminary Injunction preventing the Defendants from recouping over $10.8 million in alleged overpayments resulting in the claims disputed by Plaintiff until Plaintiff has been afforded a hearing and decision before an impartial and unbiased ALJ.

MEDICARE AND MEDICAID PAYMENT AND APPEAL PROCESS

A. The Medicare Payment Process and Post Payment Review

33. The Medicare program was enacted in 1965 under Title XVIII of the Social Security Act to provide health insurance to individuals sixty-five years of age and older. Social

Security Amendments of 1965, Pub. L. 89-97, 79 Stat. 286 (1965) (codified as amended at 42 U.S.C. § 1395-1396v). The purpose of the program is to ensure that its beneficiaries have access to health care services. *Id*. at 286. Plaintiff qualifies as a provider of home health services under Title XVIII, also known as the Medicare Act.

34. Medicare Part A, one of the four divisions of Medicare, generally covers inpatient hospital care, skilled nursing, hospice, lab tests, surgery, and home health care.

35. At issue in this matter are home health care services provided to Medicare beneficiaries.

36. To qualify for home health coverage under Medicare, a patient must be confined to the home, under the care of a physician, in need of intermittent skilled nursing services, physical therapy services, speech-language pathology services, or occupational therapy services, under a plan of care, and receiving home health services by a participating home health agency ("HHA") 42 C.F.R. § 409.42.

37. A patient is confined to the home, or home bound, if (i) the patient needs the assistance of a supportive device (e.g., a wheelchair) or the assistance of another person to leave the home, or has a condition making leaving the home medically contraindicated; and (ii) a normal inability to leave the home exists and leaving the home would require a considerable and taxing effort. CMS IOM, Publication 100-02, MBPM, Ch. 7, § 30.1.1. The patient's physician provides the certification that a patient is homebound. *Id*.

38. An initial home health certification is required for Medicare reimbursement, and a face-to-face encounter is required for this initial certification. The face-to-face encounter must occur no more than 90 days prior to the start of home health care date or within 30 days of the start of home health care. The face-to-face encounter may be performed by (i) the certifying

physician; (ii) a physician who cared for the patient in acute or post-acute care facility which directly admitted the patient to home health; (iii) a nurse practitioner or clinical nurse specialist; (iv) a certified nurse midwife; or (v) a supervised physician assistant. 42 C.F.R. § 424.22.

39. CMS reimburses Medicare providers with payments for covered claims. CMS contracts with Medicare Administrative Contactors ("MACs"), government contractors, to process and make payments on valid claims. 42 U.S.C. § 1395kk-1(a)(3). In practice, therefore, medical providers such as Plaintiff submit claims for reimbursement to the MAC appointed to its geographical area. 42 U.S.C. § 1395ff(a)(2)(A). The MAC covering Plaintiff's Medicare reimbursement during the relevant time period was Defendant Palmetto GBA, LLC.

40. Some claims that are initially paid by MACs are then subjected to an additional level of oversight through a process known as "post-payment review." During post-payment review, third party contractors audit MAC payment decisions and, frequently, reverse the MAC's decision. Post-payment review has placed a significant burden on the claim appeals process, particularly as the result of audits performed by one type of such contractor, known as a Zone Program Integrity Contractor ("ZPIC"). The ZPIC responsible for the auditing in this matter was AdvanceMed Corporation ("AdvanceMed").

41. The primary role of ZPICs is to identify cases of suspected fraud, investigate them, and take action to ensure any inappropriate Medicare payments are recouped. However, ZPICs have engaged in widespread and overzealous audits identifying what the ZPIC finds to be improper payments and forwarding this information to the MAC to request recoupment.

42. In most cases, ZPICs use statistical sampling to calculate and project the amount of overpayments made on claims. This process results in an extraordinarily large overpayment

amount derived from the findings of an audit performed on an extremely small number of claims, typically numbering around fifty (50) or less.

43. Importantly, ZPICs are paid based on the amount of Medicare reimbursement they recover from providers for these alleged improper payments, thereby making it in the ZPIC's financial interest to overturn the MAC's original payment decisions.

44. ZPIC claim denials are frequently overturned on appeal. According to data provided to the American Hospital Association ("AHA"), through the fourth quarter of 2014, hospitals reported that when they appealed post-payment auditors' denials, including up to the ALJ level, the denials were overturned sixty-nine percent (69%) of the time. *See* AHA, Exploring the Impact of the RAC Program on Hospitals Nationwide, at 33 (March 30, 2015), available at https://www.aha.org/system/files/2018-03/14q4ractractresults.pdf.

45. Before an April 2015 United States Senate hearing before the Committee on Finance, the Honorable Orrin Hatch testified that over 60% of the claims are overturned in favor of the providers when heard by an administrative law judge. *See* Opening Statement of the Honorable Orrin Hatch at April 28, 2015 Hearing before the Finance Committee of the United States Senate, Creating A More Efficient and Level Playing Field: Audit and Appeal Issues in Medicare, available at https://www.finance.senate.gov/imo/media/doc/20035.pdf.

46. This means that, on average, providers are ***over fifty-percent (50%)*** more likely to be successful at the ALJ level when compared to level one and level two of the administrative appeal process.

B. The Medicare Appeals Process

47. Pursuant to the Social Security Act, appeals of post-payment claim denials are subject to a four-level administrative appeals process, ultimately leading to a fifth level of judicial review. *See* 42 U.S.C. § 1395ff.

48. At the first level of appeal, typically referred to as the "Redetermination Level," the denied claim is presented to the MAC for redetermination. 42 U.S.C. § 1395ff(a)(3)(A). The MAC is statutorily required to issue its decision on redetermination within sixty (60) days from its receipt of the request for redetermination. *Id*. at § 1395ff(a)(3)(C)(ii). Providers are afforded one hundred and twenty (120) days from the date they receive the demand letter that initiates the appeal process to timely file their request for redetermination with the MAC, which in this case was Palmetto. 42 C.F.R. §405.942(a).

49. Pursuant to 42 C.F.R. §405.379(d)(1), Medicare contractors cannot begin recoupment proceedings on the outstanding alleged overpayment until forty-one (41) days from the date of the initial overpayment demand letter. Furthermore, Medicare contractors are required to cease all recoupment efforts once a request for redetermination is filed. 42 C.F.R. §405.379(d)(1).

50. At the second level of appeal, a provider dissatisfied with a redetermination decision may appeal the MAC's redetermination decision to a Qualified Independent Contractor ("QIC") within 180 days from the date the party received the redetermination decision. 42 C.F.R. §962(a). This level of appeal is typically referred to as the "Reconsideration Level." The QIC is statutorily required to issue its decision on reconsideration with sixty (60) days of its receipt of the reconsideration request. *Id*. at § 1395ff(c).

51. At the third level of review, typically referred to as the "ALJ Level," a provider dissatisfied with the reconsideration decision party may appeal the same within sixty (60) days of

its receipt of the QIC reconsideration decision and request a hearing before an ALJ at the OMHA. Notably, this is the first step of the appeals process at which providers historically have been able to obtain relief from adverse ZPIC determinations at levels between 60% and 72%.

52. Importantly, there is no limitation on recoupment recovery during the ALJ Level, which means that as soon as the reconsideration decision is issued, Medicare contractors may begin recoupment proceedings despite the fact the provider is waiting, three (3) to five (5) years, for a hearing at the ALJ Level.

53. If an ALJ does not hear the case and render a decision within the required 90-day period, the healthcare agency may escalate its appeal to the fourth level of review before the Medical Appeals Council, using the record established in the previous levels of review. *Id.* at § 1395ff(d)(3)(A). The Appeals Council must render a decision or remand the case within 180 days of a timely review request. 42 C.F.R. § 405.ll00(d). However, this step deprives providers of the opportunity for ALJ review, where they are most likely to have payment denials overturned.

54. If a provider is still dissatisfied after the ALJ issues its decision, the provider may appeal its claim within sixty (60) days to the Medicare Appeals Council ("Council") within the HHS Departmental Appeals Board ("DAB"). The Council is independent of both CMS and OMHA. The Council must render a decision or remand the case to the ALJ within 90 days from the date of the request for review.

55. If a provider is still dissatisfied after the DAB's level of appeal, a provider may request judicial review in a federal district court within sixty (60) days from the date of receipt of the DAB's decision.

C. Backlog of Medicare Appeals at the ALJ Level of Appeal and Resulting Delays in Adjudication Times

56. Despite the statutorily-mandated time periods governing the appeals process, in practice, it takes a provider significantly longer to fully pursue its claim through the Medicare appeals process due to the growing backlog of Medicare appeals at the ALJ Level of appeal.

57. An exponential increase in claim appeals has caused this growing delay in the Medicare appeals process, fueled in large part by the Medicare Fee-For-Service Recovery Audit Contractor Program ("RAC Program"), a demonstration program that was ultimately instituted and expanded in 2010. Under the RAC Program, aggressive government contractors, such as ZPICs, have issued numerous inappropriate claim denials, forcing a disproportionate number of providers into the Medicare appeals system to challenge these denials.

58. In fact, based on HHS's own admissions to a federal judge, the backlog of Medicare appeals shows no signs of abating anytime soon. *See Family Rehabilitation, Inc. vs. Alex M. Azar, II, et al.*, No. 17-11337 (5th Cir. March 27, 2018), citing Maria Castellucci, *HHS Says It Can't Clear Medicare Appeals Backlog by 2021 Deadline*, Modern Healthcare (Mar. 8, 2017), available at http://www.modernhealthcare.com/article/20170308/NEWS/170309902 (discussing a report by HHS made to the U.S. District Court for the District of Columbia); *see also*, *Maxmed Healthcare, Inc. v. Price*, 860 F.3d 335, 344-45 (5th Cir. 2017)(noting the serious backlog of agency appeals, the lack of resources to deal with the problem, HHS's admissions in federal court, and the "redundant, time-consuming and costly procedures" that mire providers).

59. Indeed, the number of Medicare appeals filed grew from 35,831 appeals in Fiscal Year ("FY") 2009, the last full fiscal year before the RAC Program's official expansion, to over 594,000 in FY 2017. *American Hospital Assoc. v. Sylvia M. Burwell*, Case No. 1:14-cv-00851 (D.C. App. Feb. 9, 2016), at Doc 58-1, Decl. of Jennifer Moughalian, ¶ 7.

60. Based on current data, OMHA predicts that the number of pending appeals will rise to 972,591 by the end of FY 2021 (September 30, 2021). *Id*. at ¶ 9.

61. By OMHA's own admission, the ALJs have simply been unable to keep up with the increasing volume of Medicare appeals. As provided in OMHA's September 1, 2017 status report, OMHA received 167,899 new claims for adjudication in 2017, but had been able to adjudicate only 76,000 of its total 595,000 outstanding claims. *Id*. at Ex. 1. By the time OMHA submitted its FY 2018 budget request to Congress, this backlog of pending appeals had grown to 650,000. *See* Office of Medicare Hearings and Appeals Fiscal Year 2018 Congressional Justification, at page 7, available at https://www.hhs.gov/sites/default/files/combined-office-of-medicare-hearings-and-appeals.pdf. The rate at which the ALJs can adjudicate these appeals is far below the rate at which new appeals are being filed, resulting in a long and ever-growing backlog.

62. The average processing time for adjudication of an appeal in FY 2016 was 877 days. *See id*. This number has since increased in FY 2017 to 1,051 days, with an average age of pending appeals measuring 999 days, more than 900 days past the mandatory 90-day adjudication time frame. *See id*.

63. Based on the growing numbers of appeals cited above, the predicted wait times to obtain a hearing after a case is assigned to an ALJ Plaintiff can realistically expect to wait three (3) to five (5) years, and likely longer, to obtain an ALJ hearing, much less a decision.

UNDERLYING BILLING DISPUTE

64. On March 9, 2016, AdvanceMed obtained twenty-three (23) medical records while performing an on-site audit and determined an alleged overpayment amount of a total of $59,640.99.

65. Thereafter, on February 13, 2017, AdvanceMed requested an additional 30 medical records for 30 Part A claims for a Statistical Sampling for Overpayment Estimation ("SSOE").

66. On October 25, 2017, AdvanceMed issued two (2) review results letters based on the March 9, 2016 medical record review and the February 13, 2017 medical record review. True and accurate copies of these Review Results Letters are attached hereto as Exhibits A and B.

67. As contained in the applicable Review Results Letter, upon review of the additional 30 medical records demanded in the February 13, 2017 medical record review, AdvanceMed alleged an 87% denial rate and an extrapolated Part A overpayment of $10,754,349.00.

68. On November 1, 2017, Palmetto GBA, LLC ("Palmetto") then issued an overpayment Demand Letter for $10,754,349.00, an amount which was derived from the SSOE. A true and accurate copy of which is attached hereto as Exhibit C.

69. In addition, by letter dated December 7, 2017, Palmetto issued an overpayment Demand Letter in the amount of $49,413.36, a true and accurate copy of which is attached hereto as Exhibit D.

70. The ZPIC denied the claims on several alleged grounds: (1) face to face requirements were not met; (2) skilled nursing visits were not reasonable and necessary and medically necessary; (3) physical therapy visits were not reasonable and medically necessary; (4) invalid plan of case; (5) certification requirements were not met; (6) recertification requirements were not met.

71. Notably, AdvanceMed's review was based exclusively on a retroactive record review, without any communications with, or input from, the physicians, nurses, and other health

care providers who had actually interacted with and treated the patients, or the patients' physicians who had certified and re-certified the patients' needs for home health services.

72. From these reviews of just fifty-three (53) patients, AdvanceMed and Palmetto used an unproven and non-peer-reviewed extrapolation methodology to inflate the actual, alleged overpayment amount to an extrapolated alleged overpayment amount of over $10.8 million.

73. On November 18, 2017 and December 18, 2017, Plaintiff timely filed its Requests for Redetermination with Palmetto and provided documentation supporting the medical necessity of the Part A services provided. This was Plaintiff's first level of appeal challenging the improper and unsubstantiated findings of AdvanceMed and Palmetto. True and accurate copies of these Requests for Redetermination are attached hereto as Exhibits E and F.

74. Palmetto subsequently issued unfavorable Redetermination Decisions, finding that, in conclusory fashion, the Part A services were not appropriate at the time they were rendered and, therefore, did not qualify for the home health benefit. Palmetto also rendered an unfavorable decision to Plaintiff's appeal challenging the statistical sampling used for the extrapolation. True and accurate copies of the Redetermination Decisions are attached hereto as Exhibits G and H.

75. On or about March 2, 2018 and March 28, 2018, Plaintiff timely submitted Requests for Reconsideration, Plaintiff's second level of appeal challenging the improper and unsubstantiated findings of Palmetto and AdvanceMed. True and accurate copies of the Requests for Reconsideration are attached hereto as Exhibits I and J.

76. Maximus Federal Services ("Maximus") issued unfavorable Reconsideration Decisions, finding that, in conclusory fashion, the Part A services were not appropriate at the time they were rendered and, therefore, did not qualify for the home health benefit. Maximus

also rendered an unfavorable decision to Plaintiff's appeal challenging the statistical sampling used for the extrapolation. True and accurate copies of the Requests for Reconsideration are attached hereto as Exhibits K and L.

77. On July 13, 2018, Plaintiff timely submitted requests for an ALJ Hearing, Plaintiff's third level of appeal, to challenge each of the individual claim denials that were improper and unsubstantiated, as well as the statistical methodology employed by AdvanceMed and Palmetto. True and accurate copies of the Requests for ALJ Hearing are attached hereto as Exhibits M and N.

78. Thereafter, on or about July 24, 2018, Palmetto began recouping funds from valid claims submitted by Plaintiff.

79. From July 24, 2018 until July 27, 2018, approximately $106,828.63 was recouped from Plaintiff's valid claims, resulting in an immediate loss of approximately $106,828.63 in just a few days.

80. Interestingly, Palmetto began recoupment despite Plaintiff's cease and desist to Palmetto demanding that it cease and desist from any recoupment prior to the conclusion of the ALJ appeal process, a cease and desist which was sent on June 18, 2018, a true and accurate copy of which is attached hereto as Exhibit O.

CLAIMS FOR RELIEF

81. Based on the foregoing, it is clear that Medicare, by and through its contractor, Palmetto, began recoupment of the alleged overpayment of over $10.8 million from Plaintiff.

82. Medicare receivables constitute approximately 77.6% of Plaintiff's revenues. As a result, should CMS continue with recoupment of the Redetermination Overpayment, Plaintiff will not receive any Medicare payments until the entire approx. $10.8 million has been recouped.

Plaintiff is not financially able to survive should CMS continue with recoupment of its Medicare receivables, even for just a few months, let alone the years it will take to finally receive an ALJ hearing and decision, a decision which is statistically likely to reverse the level one and level two appeal decisions.

83. As a result of the anticipated continued recoupment by CMS, Plaintiff will be forced to close its business. Its 45 employees will be out of work and forced to look for new jobs. It is doubtful that all the employees could find equivalent work in the Independence, Ohio area, which has a population of only about 7,100 and has only a few home health agencies available to both patients and nursing staff.

84. Plaintiff's patients and their families will be forced to find alternate home health providers without sufficient notice. In addition, it is not certain that the patients could find alternate home health providers that provide the unique services that Plaintiff provides. The harm to Plaintiff, its employees, its patients, and their families is therefore irreparable.

85. In light of the fact that approximately 77.6% of its revenue is derived from Medicare services, Plaintiff would also be unable to survive the extended repayment schedule routinely proposed by CMS. Unless such repayment schedule stretched over many decades (which it does not), the combination of the exorbitant recoupment amount, and the extraordinary wait time for an ALJ hearing, would render any such repayment schedule moot. Plaintiff would likely be required to pay the entire amount requested, which it cannot without going bankrupt, prior to its ALJ hearing.

86. Plaintiff has no other avenue to stay recoupment of payments to Medicare until its full evidentiary hearing before the ALJ which, again, may not be scheduled for five years or

more. Therefore, without intervention from this Court, Plaintiff will surely be out of business within a few months.

87. Separate from this action, Plaintiff is actively disputing the denial of claims through the Medicare appeals process. Plaintiff is likely to prevail, in whole or in large part, once it has presented its case to an ALJ, which will be its first opportunity to have the billing dispute heard by an impartial and unbiased party who is not affiliated with CMS.

88. Defendants' recoupment constitutes a violation of the Administrative Procedures Act in that self-help recoupment under the circumstances, where the underlying basis of the billing dispute is dubious and unlikely to withstand scrutiny by an ALJ; where the backlog at the ALJ level will delay hearing for at least three to five years; and where the recoupment would destroy Plaintiff before its first opportunity at impartial and unbiased review, is arbitrary, capricious, and characterized by abuse of discretion, and the recoupment, if not enjoined, will result in prejudice to Plaintiff's substantial rights and threaten the health and welfare of many of its patients.

89. If Defendants are not temporarily restrained and enjoined, Plaintiff will suffer immediate and irreparable harm, including the shuttering of its business, long before it has a chance to appear before an independent ALJ.

90. Plaintiff's employees and patients will suffer immediate and irreparable harm, including, but not limited to, the loss of the ability to provide unique home health services to patients in the Northeast Ohio, the loss of good will and business reputation, and ultimately, the loss of economic viability as Plaintiff will imminently be forced out of business.

91. Under these circumstances, including the extraordinary backlog of claims at the ALJ level, the administrative appeal process provided by 42 C.F.R. § 405.1000, et seq., does not

afford an adequate remedy at law because recoupment would force Plaintiff to close long before it could ever receive an ALJ hearing – much less proceed to the remaining two levels of the appeals process. The deprivation of any effective relief prior to Plaintiff's bankruptcy, is even more inadequate in light of the substantial likelihood that the underlying billing dispute supporting the recoupment would ultimately be resolved, in whole or in part, in Plaintiff's favor.

92. Plaintiff's Medicare payments, its legitimate expectations for receipt of Medicare payments for services provided to patients who are unable to leave the home in order to obtain needed home health services, and its interest in engaging in the home health business and maintaining the goodwill associated therewith, constitute valuable property and liberty rights and interests within the meaning and protection of the Due Process Clause of the Fifth Amendment and Fourteenth Amendments to the United States Constitution.

93. The requested relief will not adversely affect any public interest. The government has not alleged that Plaintiff committed any fraud, that home health services were not provided as billed, or that there were deficiencies or issues with the quality of the services provided. The only prospect of harm here is the harm to Plaintiff if the requested relief is not granted. That harm unfortunately, is fatal to Plaintiff and would result in the complete loss of its business. The balance of the harms clearly favors Plaintiff, its employees, and its patients, while CMS cannot demonstrate any harm to the United States if a temporary restraining order and injunction are issued.

94. Moreover, Plaintiff is likely to succeed on the merits. The billing dispute underlying the threatened recoupment is premised entirely on a difference of clinical opinion between the physicians and other caregivers who treated the patients at issue and the unidentified reviewers who have relied strictly on a paper record. Furthermore, the methodology upon which

Defendants seek over $10.8 million from Plaintiff is severely flawed and fails to meet peer-reviewed statistical standards.

95. Plaintiff seeks only to preserve the status quo pending the outcome of a hearing before an ALJ. Plaintiff therefore seeks a Temporary Restraining Order and an injunction preventing the Defendants from recouping from Plaintiff's Medicare payments prior to a decision from an unbiased and impartial ALJ on the merits of the billing dispute.

96. Defendants should be enjoined from (1) recouping from Plaintiff's Medicare payments based on a billing dispute for which Plaintiff is highly likely to prevail and (2) imposing irreparable harm on Plaintiff by forcing its closure, thereby subjecting its patients and their families to try to locate other home health services and agencies which do not provide the full array of services provided by Plaintiff.

COUNT ONE – PROCEDURAL DUE PROCESS

97. Plaintiff restates each and every preceding allegation of the Complaint as if fully stated herein.

98. The procedures utilized by CMS to recoup substantial, alleged overpayments from Plaintiff based on the determinations of entities that have an established track record of overstating overpayments, when Plaintiff has a substantial likelihood of success in overturning the denials of payment, are constitutionally inadequate, because they force Plaintiff out of business before it can even access the appeals process.

99. To satisfy the requirements of due process, the HHS Secretary is statutorily required to provide a home health agency with an administrative hearing and an opportunity to challenge the overpayment determinations before a fair and impartial decision maker prior to imposing a self-help recoupment remedy that would force Plaintiff out of business, at least

where, as here, the home health agency has demonstrated significant reason to doubt the validity of the alleged overpayment determinations underlying the threatened recoupment.

100. Defendants are threatening to deprive Plaintiff of its property and liberty interests in or associated with its Medicare payments and home health business and goodwill without due process of law, in violation of the Fifth and Fourteenth Amendments of the United States Constitution and other applicable law.

101. Such action threatens to cause irreparable harm to Plaintiff.

102. The issuance of injunctive relief prohibiting such recoupment until such due process has been had will not harm the Defendants and is in the public interest.

COUNT TWO – SUBSTANTIVE DUE PROCESS

103. Plaintiff restates each and every preceding allegation of the Complaint as if fully stated herein.

104. It would be a clear abuse of discretion, and arbitrary and capricious action, for Defendants to withhold Plaintiff's Medicare payments pending a hearing before an ALJ under the circumstances of this case. HHS's forcing of a home health care provider out of business on the basis of a billing dispute that is premised on determinations and statistical extrapolation created by an entity with an established track record of overstating overpayments, and where Plaintiff has demonstrated a likelihood of reversing those determinations and the extrapolation at an ALJ hearing, would be irrational.

105. Defendants' arbitrary and capricious decision to recoup Plaintiff's Medicare payments and drive it out of business under the circumstances of this case deprives Plaintiff of its liberty and property interests, in violation of due process under the Fifth and Fourteenth Amendments to the United States Constitution and other applicable laws.

106. Such action threatens to cause irreparable harm to Plaintiff and its patients and their families.

107. The issuance of injunctive relief prohibiting such recoupment will not harm the Defendants and is in the public interest.

COUNT THREE – DECLARATORY JUDGMENT

108. Plaintiff restates each and every preceding allegation of this Complaint as if fully stated herein.

109. Pursuant to 28 U.S.C. §2201, "[i]n a case of actual controversy within its jurisdiction,…any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such." *See also*, Rule 57 of the Federal Rules of Civil Procedure.

110. The controversy between the parties must necessarily be "of a justiciable nature," thus excluding an advisory decree upon a hypothetical state of facts. *Ashwander v. Tennessee Valley Authority*, 297 U.S. 288, 325, 56 S.Ct. 466 (1936).

111. Defendants are required to provide Plaintiff with an ALJ hearing and decision within ninety (90) days of its request. 42 U.S.C. § 1395ff(d)(1)(a); 42 C.F.R. § 405.1016(a).

112. An ALJ hearing and decision in this matter will not occur within ninety (90) days of Plaintiff's request for ALJ hearing.

113. Nevertheless, despite Defendants' failure to adhere to these statutorily mandated requirements and their deprivation of Plaintiff's due process rights, it is engaged in the process of

recouping over $10.8 million from Plaintiff, despite the fact Plaintiff is unable to defend its position in front of a neutral, unbiased ALJ.

114. Defendants are recouping from Plaintiff's Medicare payments even though they cannot and will not provide the ALJ hearing in the statutorily required time frame.

115. This action by Defendants has created a real and justiciable controversy between Plaintiff and Defendants, whereby this Court should enter a declaratory judgment against Defendants mandating that recoupment cannot begin until Plaintiff has the opportunity for a hearing and decision before the ALJ.

COUNT FOUR – ULTRA VIRES

116. Plaintiff restates each and every preceding allegation of this Complaint as if fully stated herein.

117. Defendants are required to provided Plaintiff with an ALJ hearing and decision within ninety (90) days of its request. 42 U.S.C. §1395ff(d)(1)(A); 42 C.F.R. §405.1016(a).

118. Defendants are threatening to recoup from Plaintiff's payments even though they cannot and will not provide the ALJ hearing in the statutorily required time frame. The Court should enjoin Defendants from engaging in such ultra vires actions against Plaintiff, which actions are contrary to the limitations on the Defendants' authority as set forth in the Medicare Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

1. That the Court issue a Temporary Restraining Order, Preliminary Injunction and Permanent Injunction prohibiting the Defendants from recouping from Plaintiff's Medicare payments prior to the completion of the administrative process. Plaintiff has

meritorious challenges to the billing dispute underlying the threatened recoupment from Medicare payments, and will vigorously assert its arguments during the administrative appeals process that has already been initiated as promptly and expeditiously as the ALJ can accommodate. In the interim, if immediate injunctive relief is not granted, Plaintiff's right to judicial review in this Court at the conclusion of the administrative process will be eliminated by the inability of Plaintiff to remain in existence due to the crippling effect of the threatened Medicare recoupment. Furthermore, Plaintiff's employees and patients will suffer irreparable harm in the absence of an injunction;

2. Enter Judgment in Plaintiff's favor;
3. Award Plaintiff's costs as allowable by 28 U.S.C. § 1920, and attorneys' fees as allowable by statute, if any, including for example the Equal Access to Justice Act, 28 U.S.C. § 2412(d)(1)(A) based upon a finding that the Defendants' position is not substantially justified; and
4. That the Court issue and award Plaintiff such other and further relief as the Court deems just and proper.

Respectfully Submitted,

/S/ John N. Childs

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